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10/665,431	09/22/2003	Paul C. Weaver	8932-807-999	6518
51832	7590	08/07/2006	EXAMINER	
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			SWIGER III, JAMES L	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/665,431

Applicant(s)

WEAVER ET AL.

Examiner

James L. Swiger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,9,19,20,30,31,41,42,51 and 52 is/are allowed.
- 6) ☒ Claim(s) 1-10, 11-21, 22-32, 33-43, and 44-54right is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 4/26/2006 have been fully considered but they are not persuasive.

With regards to applicant's arguments regarding Claim 44 and the Baccelli (US Patent 6,306,136), applicants submit that the reference does not teach a first threaded hole and a second non-threaded hole. Whether the holes are renamed as a "first" or "second" hole, the reference still reads on the specified type of hole as shown in the previous rejection. Baccelli discloses at least one first threaded hole (111) and a least one second non-threaded hole (121). Also, applicant's submit that Baccelli does not disclose a screw with a non-threaded upper portion of the shaft for non-locking engagement. Compared to the fully threaded screw of Fig. 4, Fig. 5 discloses a screw (23') that has a non-threaded upper portion, capable of a non-locking engagement with the plate.

With regards to the arguments directed to claims 1, 11, 22 and 33, wherein the holes that are renamed as a "first" or "second" hole in the present amendment, the reference of the combination of Kyle et al. (US Patent 5,749,872) and Trebing et al. (US Patent 5,601,553) and still reads on the specified type of hole as shown in the previous rejection. Further, the screws are capable of remaining in their respective "first" and "second" holes for substantially as long as the bone plate is implanted if the user chooses to do so and is considered functional in regards to the use of the screws. .

Further, it is noted that the law of anticipation does not require that the reference "teach"

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what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. In this case it is the fact that there is a first threaded hole and a second non-threaded hole. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

With regards to the argument regarding claims 1, 11, 22 and 33 where In response to applicant's argument that the examiner has combined the references improperly because of a discrepancy between the use of temporary screws and/or the permanent lag screws, the examiners asserts that the intention of combining the references was to show the types of holes that are part of a combined view of the references. As stated above, the use of the screws is considered functional, if the user wishes to use them temporarily or in a permanent fashion. However the rejection still stands in the previous rejection as readable on the references.

In light of the above reasons, the following rejections still apply.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

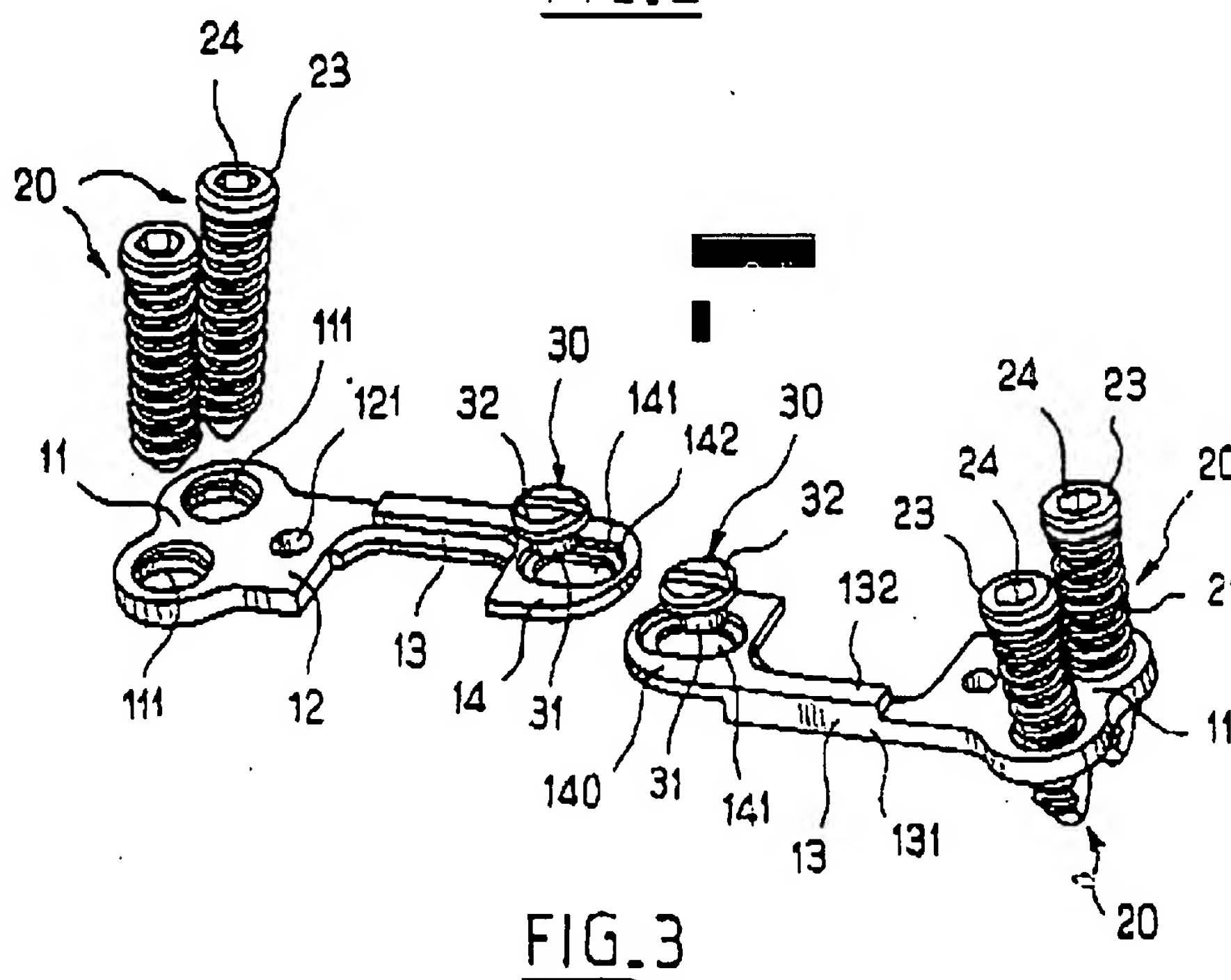
A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

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filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 44 is rejected under 35 U.S.C. 102(e) as being anticipated by Baccelli (U.S. Patent No. 6,306,136). Baccelli discloses a device having a plate (10) having an upper surface (11) and a lower surface (See Fig. 3 below)



with at least one (or a first) threaded hole (111) passing through the upper and lower surfaces, and one (or a second) non-threaded hole (121) passing through the upper and lower surfaces, and a first and second screw to be used in engaging the bone (20). The device further includes screws (20) having threaded and non-threaded shafts and non-threaded heads (See Fig. 4).

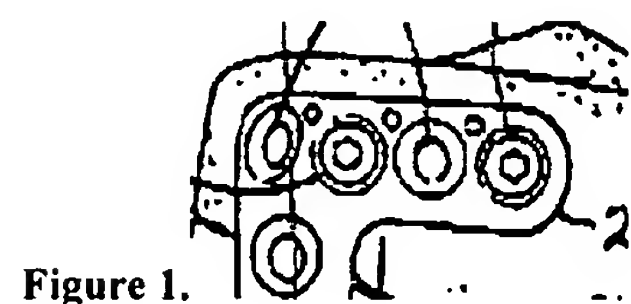
***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **45-46 and 48-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Baccelli '136 in view of Winqvist et al (U.S. Pat. Pub 2002/0013587). Baccelli discloses the claimed invention except for a flared head, that is twisted, curved, and having at least one suture hole.

Winqvist et al. teaches a device having a head portion that is flared (14), a shaft portion (22), a head portion that is twisted and curved (See device profile in Figure 4), and at least one suture hole (See Fig. 1 below). The above modifications aid in improved alignment and securing of the articular surface at the joint of the bone, thereby inhibiting premature wear of the bone [par 0016]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Baccelli having a head portion that is flared (14), a shaft portion (22), and a head portion that is twisted and curved (see device profile in Fig. 4), and at least one suture hole (see Fig. 1) in view of Winqvist et al. in order to better align and attach the device to the bone.



Claim 47 rejected under 35 U.S.C. 103(a) as being unpatentable over Baccelli '136 in view of Winqvist et al. '587 as applied to claim 45 above, and further in view of Kyle et al (U.S. Patent No. 5,749,872).

Baccelli in view of Winqvist et al. discloses the claimed device except for a device having tapered head. Kyle et al. teaches a device having a tapered head (50) that further provides a buttressing surface for abutting femur adjacent condyles (Col. 3, lines 58-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Baccelli in view of Winqvist et al. including a tapered head (50), and further in view of Kyle et al. to better fit the condylar surface.

Claim 50 rejected under 35 U.S.C. 103(a) as being unpatentable over Baccelli '136 in view of Winqvist et al. '587 as applied to claim 45 above, and further in view of Berger et al. (U.S. Patent No. 5,674,222). Baccelli in view of Winqvist et al. disclose the above invention except for a shaft portion that terminates into a tapered tail. Berger et al teaches a tapered tail (see Fig. 7 below) that reduces bone contact for improved healing of the bone (Col. 2, lines 32-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Baccelli in view of Winqvist et al having a tapered end, further in view of Berger et al. to have improved bone healing.



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Figure 7.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baccelli '136 in view of Winqvist et al. '587 as applied to claim 45 above, and further in view of Trebing et al (U.S. Patent No. 5,601,553). Baccelli in view of Winqvist et al. disclose the above device except for a device having a first (14) and second threaded hole (13) with a converging axes of the screws. (See Fig 2 below)

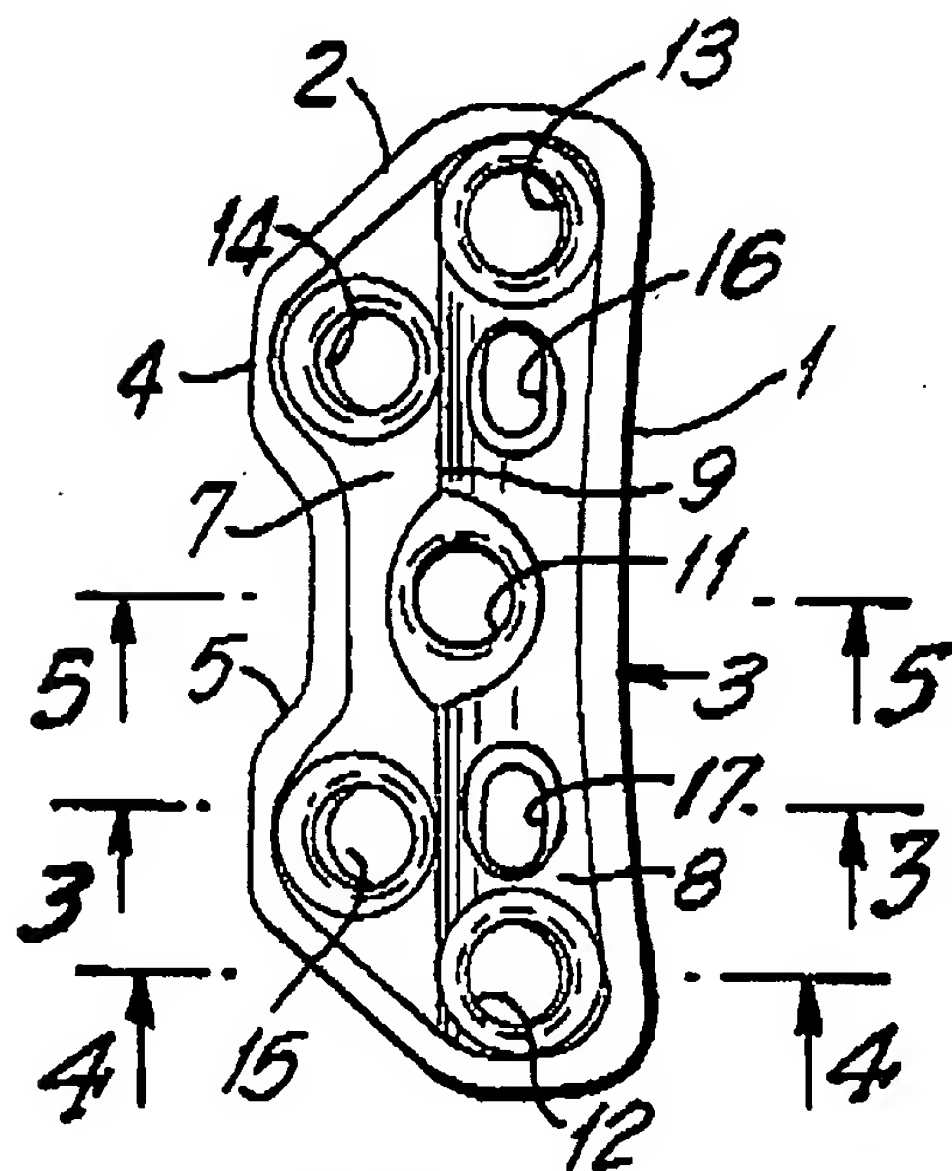


FIG. 1

Trebing et al. teaches a head portion a head with a first (14) and second threaded hole (13) and a converging axes of screws (see Fig. 8 of Trebing et al.). The purpose having a converging axes allows the creation of a conical bone plug, rendering the plate more difficult to dislodge under load, better securing the plate (Col. 3, lines 6-



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12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Baccelli in view of Winqvist et al. including at least a converging axes of screws (see Fig. 8 of Trebing et al), further in view of Trebing et al. to have a better securing process, and less movement after installation.

Claim **54** is rejected under 35 U.S.C. 103(a) as being unpatentable over Baccelli '136 in view of Karas et al. (U.S. Patent No. 4,867,144). Baccelli discloses the claimed invention except for at least one threaded hole having a double lead thread. Karas et al. teaches a plate having a double lead thread in its design for the purpose of better securing the locking screws in the plate at the proper angles needed, and to prevent unnecessary pressure between the plate and bone that would prevent bone growth (Col. 2, lines 14-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Kyle et al. in view of Trebing et al. having at least a hole with a double thread and further in view of Karas et al. to better secure the device and improve bone growth.

Claims **1, 5, 10-11, 15, 21, 33, 37 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al (U.S. Patent No. 5,749,872) in view of Trebing et al. (U.S. Patent No. 5,601,553). Kyle et al. discloses a device having a plate (see Fig. 2), an upper surface (76) a lower surface (74), a first and second screw (See Figs. 8 and 9, and item 30), a head portion (44), and a shaft portion (80), and an anterior and posterior fork in the head (88 and 90), a curved surface (see bottom half of plate in Fig. 1), a

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tapered head portion (50), and a head portion that flares outward from the shaft (Fig. 4).

Kyle et al. does not disclose, however, holes where the axes converge, and where the shaft has one (first) threaded and one (second) non-threaded hole. Trebing et al. teaches a converging axes of screws (see Fig. 8), and a shaft with one threaded and one non-threaded hole (12 and 17). The purpose having a modification/pairing of screw holes in the shaft would be to facilitate the securing process of the plate to the bone area (Col. 1, lines 50-61), while the purpose of the converging axes allows the creation of a conical bone plug, rendering the plate more difficult to dislodge under load, better securing the plate (Col. 3, lines 6-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Kyle et al. having a shaft with threaded and non threaded screw holes and a converging axes of the screw holes to better facilitate the securing of the bone plate to the specified area of the femur.

Claims **2, 12, and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. '872 in view of Trebing et al. '553 as applied to claims 1, 11, and 33 above, and further in view of Karas et al. (U.S. Patent No. 4,867,144)

Kyle et al. '872 in view of Trebing et al. '553 disclose the claimed invention except for a device having a double lead thread. Karas et al. teach a device having a double lead thread in its design for the purpose of better securing the locking screws in the plate at the proper angles needed, and to prevent unnecessary pressure between the plate and bone that would prevent bone growth (Col. 2, lines 14-31). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Kyle et al. in view of Trebing et al. having at least a hole with a double thread and further in view of Karas et al. to better secure the device and improve bone growth.

Claims **3, 13, and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. '872 in view of Trebing et al. '553 as applied to claims 1, 11, and 33 above, and further in view of Gley (U.S. Patent No. 3,630,261). Kyle et al. in view of Trebing et al. disclose the claimed invention except for a screw having a double lead thread. Gley discloses a fastener with double threads that provides a positive frictional lock in an infinite number of relative positions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Kyle et al. in view of Trebing et al. having at least a double-threaded screw and further in view of Gley to better secure and fasten the bone plate the target bone area.

Claims **4, 6, 14, 16-17, 26, 32, 36 and 38-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. '872 in view of Trebing et al. '553 as applied to claims 1, 11, and 33 above, and further in view of Winqvist et al. (U.S. Pub No. 2002/0013587).

Kyle et al. '872 in view of Trebing et al. '553 disclose the claimed invention except for a device having a twisted, curved head, with suture holes. Winqvist et al. teaches a device having a head portion that is twisted and curved (See device profile in Figure 4), and at least one suture hole (See Fig. 1 above). The above modifications aid

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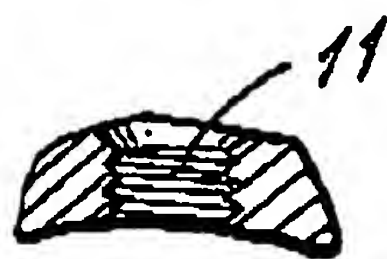
in improved alignment and securing of the articular surface at the joint of the bone, thereby inhibiting premature wear of the bone [par 0016]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the plate of the combination of Kyle et al. as modified by Trebing et al. having a twisted, curved head with suture holes further in view of Winqvist et al. in order to improve the securing of bone.

Claims **7,18, and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. '872 in view of Trebing et al. '553 as applied to claims 1,11, and 33 above, and further in view of Berger et al. (U.S. Patent No. 5,674,222).

Kyle et al. '872 in view of Trebing et al. '553 disclose a the claimed device except for the shaft portion terminating in a tapered tail. Berger et al. teaches a tapered tail (see Fig. 7 above) that reduces bone contact for improved healing of the bone (Col. 2, lines 32-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the plate of the combination of Kyle et al. as modified by Trebing et al. with the shaft portion terminating in a tapered tail in view of Berger et al. in order to have an invention for improved bone healing.

Claims **22 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Trebing et al. '553. in view of Berger et al. '222. Trebing et al. discloses a device having a bone plate (see Fig. 2), an upper surface (6), a lower surface (See Fig. 5 below)

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**FIG. 5**

and at least one (first) threaded (13) and one (second) non-threaded hole (16) that passes through the upper and lower surfaces, a first screw (Fig. 7) and a second screw that, combined, remain in their respective holes as long as the bone plate is implanted. Even though only one screw is shown (Fig. 7) in the drawings, it is implied by the nature of the invention, that it requires a second screw for attachment. Trebing et al. further discloses a head and shaft portion of the device (See Fig. 2 above).

Trebing et al. does not disclose a cross-section shape that resembles that of a trapezoid. Berger et al. discloses a trapezoidal shape in its shaft region (Fig. 1A). The trapezoidal shape allows for minimal contact with the bone to allow for improved healing of the area of fractured bone in combination with the plate (Col. 2, lines 32-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Trebing et al. having a trapezoidal shaft shape in view of Berger et al. to minimize contact with the bone for improved healing.

Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trebing et al. '553 in view of Berger et al. '222 as applied to claim 22 above, and further in view of Karas et al. (U.S. Patent No. 4,867,144) Trebing et al. in view of Berger et al. discloses the claimed invention except for at least a threaded hole. Karas et al. teaches a plate having a double lead thread in its design for the purpose of better securing the

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locking screws in the plate at the proper angles needed, and to prevent unnecessary pressure between the plate and bone that would prevent bone growth (Col. 2, lines 14-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Trebing et al. as modified by Berger et al. having at least a double threaded hole in view of Karas et al. to better secure the plate.

Claim **24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Trebing et al. '553 in view of Berger et al. '222 as applied to claim 22 above, and further in view of Gley (U.S. Patent No. 3,630,261). Trebing et al. '553 in view of Berger et al. '222 disclose the claimed invention except for the first screw having a double lead thread. Gley discloses a fastener with double threads that provides a positive frictional lock in an infinite number of relative positions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Trebing et al. in view of Berger et al. having at least a double-threaded screw and further in view of Gley to better secure and fasten the bone plate the target bone area.

Claims **25, and 27-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Trebing et al. '553 in view of Berger et al. '222 as applied to claim 22 above, and further in view of Winkvist et al. '587. Trebing et al. in view of Berger et al. discloses the claimed invention except a twisted, curved head portion or a suture hole. Winkvist et al. teaches a device having a head portion that is twisted and curved (See device profile in Figure 4), and at least one suture hole (See Fig. 1 above). The above modifications aid in improved alignment and securing of the articular surface at the joint of the bone, thereby inhibiting premature wear of the bone [par 0016]. It would have been obvious to

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one having ordinary skill in the art at the time the invention was made to construct the device of Trebing et al. as modified by Berger et al. with at least a head portion that is twisted and curved with at least one suture hole and further in view of Winkvist to prevent premature wear of the bone.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 11, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 17 and 18, respectively of U.S. Patent No. 6,623,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "bone contacting surfaces" mentioned in the U.S. Patent '486 are the same functional equivalent of the "lower surface" in the current application. With regards to a plurality of first and second holes in the above



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U.S. Patent '486, the current application could encompass the plurality of holes in the above patent, as it states that "at least" one threaded hole, and one non-threaded hole is present in the bone plate. "At least" one implies there may be more holes present, and thus a plurality of holes. Therefore, the above claims are rejected as being substantially similar to the previously issued claims on the above U.S. Patent No. 6,623,486.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-


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5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLS

 7/26/06

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER